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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,694	12/21/2004	Michael Chopp	1059.00106	2465

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EXAMINER	
WEBB, WALTER E	
ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,694	CHOPP, MICHAEL	
	Examiner	Art Unit	
	Walter E. Webb	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-13 are pending.

Claims 1-13 are rejected.

Claim Rejections - 35 USC § 112

1. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-13 are drawn to a method of promoting neurogenesis or increasing neurological function by administering a phosphodiesterase inhibitor and cellular therapy.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, applicant discloses isolation and culture of mesenchymal stem cells, and how phosphodiesterase inhibitors can be used to promote neurogenesis in rats, but not a patient in need of neurogenesis. There is no mention of how mesenchymal stem cells can be used to promote neurogenesis to a

patient in need of neurogenesis promotion. There are also no working examples of stem cells combined with a phosphodiesterase inhibitor promoting neurogenesis or increasing neurological function. Therefore, a method of administering the combination of the phosphodiesterase inhibitor and/or cellular therapy to a patient in need thereof is not supported in the specification. Because there are no working examples described in correlation to the claims, there is uncertainty as to the promotion of neurogenesis or increasing neurological function in a patient with the phosphodiesterase inhibitor and/or cellular therapy.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham (US 6,075,028).

Claims 1, 8, 10 and 12 are drawn to a method of promoting, augmenting the production of neurons and increasing neurological function (neurogenesis) comprising administering a therapeutic amount of a phosphodiesterase inhibitor compound to a patient in need of such treatment. Claims 3 and 5-7 are drawn to a compound that is a phosphodiesterase inhibitor, sildenafil, and augments nitric oxide in a tissue in a pharmaceutically acceptable carrier for promoting neurogenesis.

Graham teaches a method of using a phosphodiesterase, sildenafil, to treat Tourette's syndrome and other related central nervous system (CNS) disorders. (See col. 2 lines 10-16 and claim 1.) Promotion of neurogenesis and increasing neurological function would inevitably be involved by this treatment, since someone having Tourette's would be in need of neurogenesis promotion.

It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from

prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641,644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) ("mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex, 309 F.2d 488,492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957) ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). The intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since PDE inhibitor, sildenafil, is capable of performing the intended use of promoting neurogenesis and increasing neurological function by augmenting nitric oxide in the tissue, then it meets the claims.

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Pittenger (US 5,827,740).

Claims 3 and 4 are drawn to a compound of a phosphodiesterase inhibitor including a cellular therapy. Applicant defines cellular therapy as stem cells. (See pp. 9 of Specification.)

Pittenger claims a composition of stem cells and a phosphodiesterase inhibitor. (See col. 2 lines 40-45 and col. 14 lines 1-5.) With every limitation met by Pittenger, claims 3 and 4 are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US 6,075,028) in view of Price (WO 200050568).

Claims 1-13 are drawn to a compound and method of promoting neurogenesis or increasing neurological function that includes a phosphodiesterase inhibitor and cellular therapy.

Graham teaches treating Tourette's syndrome by administering sildenafil. (See col. 2 lines 10-16 and claim 1.) Since someone having Tourette's would be in need of neurogenesis promotion, then it meets this limitation. See also in Graham that

neurotransmission dysfunction is implicated with Tourette's, and Alzheimer's is also associated with neurotransmission dysfunction. (See col. 1 lines 25-35.)

Graham does not teach the use of cellular therapy.

Price teaches a method of promoting neurogenesis or increasing neurological function (since they treat Alzheimer's) that includes cellular therapy. (See p. 1 lines 25-30.)

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to use the cellular therapy of Price with the sildenafil of Graham since Price discloses its invention is useful in treating Alzheimer's, and Graham teaches that Tourette's, as well as Alzheimer's, is implicated in neurotransmission dysfunction. (See Graham col. 1 lines 25-35; see Price p.2 lines 13-20.) Thus, Graham teaches that sildenafil can also be used for treating Alzheimer's. Price and Graham use cellular therapy and sildenafil individually in the art for the same purpose, namely, to treat Alzheimer's.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

No claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 272-1600. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

WW

MICHAEL MELLER
PRIMARY EXAMINER